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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/576,097 05/22/00 ALANI

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023492
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HM22/0417

EXAMINER

LUKTON, D

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

04/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/576,097

Applicant(s)

Alani

Examiner

David Lukton

Group Art Unit

1653



☒ Responsive to communication(s) filed on May 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-19 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-19 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

G1: the HIV protease inhibitor is one of those specifically recited in claims 2-4;

G2: the HIV protease inhibitor can be any that is encompassed by claim 1, with the proviso that G1 is excluded;

G3: the solvent comprises a fatty acid and ethanol, and a surfactant is not present;

G4: the solvent comprises a fatty acid and ethanol, and a surfactant is present;

G5: the solvent comprises a fatty acid and propylene glycol, and a surfactant is not present;

G6: the solvent comprises a fatty acid and propylene glycol, and a surfactant is present.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-11, drawn to compositions in which the inhibitor is limited to G1, and the solvent and surfactant can vary as the claims permit.
2. Claims 1, 5, 7-9, drawn to compositions in which the inhibitor is limited to G2, and the solvent/surfactant is limited to G3.
3. Claims 1, 5-9, drawn to compositions in which the inhibitor is limited to G2, and the solvent/surfactant is limited to G4.

4. Claims 1, 5, 7-9, drawn to compositions in which the inhibitor is limited to G2, and the solvent/surfactant is limited to G5.
3. Claims 1, 5-9, drawn to compositions in which the inhibitor is limited to G2, and the solvent/surfactant is limited to G6.

Claims 12-19 are not grouped. These claims will be rejoined with the elected invention. The claimed inventions are distinct.

To the extent that the claims are limited to the HIV protease inhibitors recited in claims 2-4, no restriction is imposed. The restriction applies to the vast array of compounds which have been asserted in the prior art to be HIV protease inhibitors. Clearly, the protease inhibitors themselves are not novel. Novelty, to the extent that it may exist, resides in the ternary mixture of the inhibitor, the fatty acid, and ethanol or propylene glycol. However, it is not uncommon for a reference to suggest either or both of these carriers; moreover, all embodiments are at least *prima facie* obvious, since the carriers at issue are sufficiently common that the pharmaceutical formulation specialist of ordinary skill would have had reason to employ them.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific HIV protease inhibitor.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1653